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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,466	09/12/2000	Dinesh Mody	FMTIP029	6579

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EXAMINER

ROANE, AARON F

ART UNIT PAPER NUMBER

3739

DATE MAILED: 07/25/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/660,466

Applicant(s)

MODY ET AL.

Examiner

Aaron Roane

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-39,41-46,51,53,57,66,67,76,78-86,89-91 and 100-104 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-39,41-46,51,53,57,66,67,76,78-86,89-91 and 100-104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 78-86 and 89-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481

Art Unit: 3739

(Bd. App. 1949). In the present instance, claim 78 recites the broad recitation of an “**organ or duct**”, and the claim also recites “**inner wall of a heart**” which is the narrower statement of the range/limitation.

For the purpose of examination, the examiner will treat claim 78 in its original form.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 92-96 have been renumbered 100-104. Here follows the claim dependency of claims 100-104

<u>Claim</u>	<u>Dependency</u>
100	Independent
101	Depends on 100
102	Depends on 100

Art Unit: 3739

103 Depends on 102

104 Depends on 103

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 36, 53, 57, 66, 67, 76 and 100 are rejected under 35 U.S.C. 102(e) as being anticipated by Berube et al. (USPN 6,325,796 B1).

Regarding claims 36, 57, 66, 67, 76 and 100, Berube et al. disclose a microwave ablation assembly comprising an elongate antenna device (30) electrically coupled to the distal end of a coaxial transmission line having an inner (31) and outer (32) separated by a dielectric medium (33), the coaxial transmission line is connected to a microwave energy source (inherent), an introducer or elongate probe (21) that carries a portion of the antenna device (30) within a lumen having a sharpened distal end and allowing for the slidable displacement of the antenna device beyond the distal end of the probe, see

Art Unit: 3739

abstract, col. 6 and 7 and figures 1-5. Here the antenna device and the transmission line make up the microwave energy delivery means.

Regarding claims 41-44, 46 and 101-14, Berube et al. disclose the claimed invention, see figure 6. Here the biasing element is the bend in the probe.

Regarding claim 51, Berube et al. disclose the claimed diameter, see starting col. 5, line 63 and ending on col. 6, line 1.

Claims 78-86 and 89-91 are rejected under 35 U.S.C. 102(e) as being anticipated by Gough et al. (USPN 5,863,290).

Regarding claims 78-86, Gough et al. disclose a microwave ablation system (see third the paragraph beginning after the "summary of the invention" and the later discussion of the connection to the microwave energy source 20) as seen in figures 3-8 comprising an ablation device (16) that includes an energy delivery portion and an introducer (14) having a sharpened distal end and that is sized and dimensioned for slidable receipt of the ablation device therethrough. As seen for example in figure 3 (and explained in column 6, lines 30-60), the energy delivery device is made of a nitinol material and is selectively deployed to attain multiple shapes and sizes ranging from only "a few degrees from the longitudinal axis" to an obtuse angle embodiment described as a "j-hook" type.

Art Unit: 3739

Regarding claims 89-91, Gough et al. disclose the claimed invention. It is the examiner's position that these claims are only directed to the intended use of the present application and do not recite actual structure. Accordingly the reference of Gough et al. is seen to meet the limitations of these claims. Finally, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The Gough et al. device is capable of conforming to the wall of an organ or duct.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berube et al.

(USPN 6,325,796 B1) in view of being well known in the art and Lundquist et al. (USPN 5,531,677).

Art Unit: 3739

Regarding claims 37-39, Berube et al. disclose the claimed invention except for providing a steering mechanism and the ability to bend the ablation means at an angle in the range of 0° to 90° or 45° to 135° with respect to the longitudinal axis of the introducer. It is well known in the art to provide an ablation catheter or probe with a steering or deflection means such that the distal end of the catheter or probe, which is where the ablation element is located, can be deflected or bent in such a manner as to place the distal end portion of the catheter or probe in close proximity to and parallel with adjacent tissue to be treated. As shown by Lindquist et al., who disclose an ablation catheter and teach the use of a steering or deflecting means (12 and 48) that bends the distal end portion of the catheter (4) at an angle in the range of 0° to 90° or 45° to 135° with respect to its unbent longitudinal axis such that the distal end of the catheter or probe, which is where the ablation element is located, can be deflected or bent in such a manner as to place the distal end portion of the catheter or probe in close proximity to and parallel with adjacent tissue to be treated.

Response to Amendment

As to the remarks regarding claims 37, 57, 76 and 100 and the claims dependent upon them, the examiner has applied different art due to the amendments. The remarks presented in the amendment which point out the deficiencies in the Gough et al. reference are acknowledged.

Art Unit: 3739

As to the remarks to the rejections of claims 78-91, the amendment to claim 78 was improper since it recited a narrow limitation within a broad limitation. Furthermore, the amendment was directed to intended use and supplied no distinguishing features over the Gough et al. reference. In apparatus claims, limitations must supply, provide, imply or suggest structural features that clearly distinguish over the art. Otherwise, the recited limitations are not viewed as distinct over the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3739

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A.R. *A.R.*
July 18, 2003

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER